UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

AZURITY PHARMACEUTICALS, INC., *Plaintiff*, v. BIONPHARMA INC., *Defendant*.	C.A. No. 21-1286-MSG C.A. No. 21-1455-MSG

DEFENDANT BIONPHARMA'S OPPOSITION TO PLAINTIFF AZURITY'S MOTION TO DISMISS BIONPHARMA'S COUNTERCLAIMS OR, IN THE ALTERNATIVE, TO BIFURCATE AND STAY THEM

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TABLE OF ABBREVIATIONS

Abbreviation	Meaning
’008 patent	U.S. Patent No. 9,669,008 B1 (D.I.[1] 9-3, 7/13/21 Shrestha Decl. Ex. C)
’023 patent	U.S. Patent No. 11,040,023 B2 (D.I. 89-1, First Am. Compl. Ex. A)
’405 patent	U.S. Patent No. 11,141,405 B2 (D.I. 1, Compl. Ex. A)
’442 patent	U.S. Patent No. 9,808,442 B2 (D.I. 9-4, 7/13/21 Shrestha Decl. Ex. D)
’482 patent	U.S. Patent No. 10,786,482 B2 (D.I. 9-12, 7/13/21 Shrestha Decl. Ex. L)
’621 patent	U.S. Patent No. 10,918,621 B2 (D.I. 9-13, 7/13/21 Shrestha Decl. Ex. M)
’745 patent	U.S. Patent No. 10,039,745 B2 (D.I. 9-5, 7/13/21 Shrestha Decl. Ex. E)
’868 patent	U.S. Patent No. 10,772,868 B2 (D.I. 9-11, 7/13/21 Shrestha Decl. Ex. K)
’987 patent	U.S. Patent No. 10,154,987 B2 (D.I. 9-6, 7/13/21 Shrestha Decl. Ex. F)
ANDA	Abbreviated New Drug Application pursuant to 21 U.S.C. § 355(j)
Azurity	Plaintiff Azurity Pharmaceuticals, Inc., successor-in-interest to Silvergate Pharmaceuticals, Inc.
Azurity’s Brief	Plaintiff Azurity Pharmaceuticals, Inc.’s Opening Brief in Support of Its Motion to Dismiss Bionpharma’s Counterclaims or, in the Alternative, to Bifurcate and Stay Them. D.I. 149; 21-1455 D.I. 61
Azurity’s enalapril liquid patents	’008, ’442, ’745, ’987, ’482, ’868,’621, ’023, and ’405 patents

[1] All “D.I.” references in this table and throughout the instant Opposition are to the 21-1286 docket unless otherwise specified.

Abbreviation	Meaning
Azurity's Motion or Azurity's MTD	Plaintiff Azurity Pharmaceuticals, Inc.'s Motion to Dismiss Bionpharma's Counterclaims or, in the Alternative, to Bifurcate and Stay Them. D.I. 148; 21-1455 D.I. 60
Azurity's TRO/PI Motion	21-1286 D.I. 24, Azurity's Motion for Order to Show Cause for Temporary Restraining Order, Preliminary Injunction, and Other Emergent Relief
Bionpharma	Defendant Bionpharma Inc.
Bionpharma's ANDA	Bionpharma's ANDA No. 212408
Bionpharma's First Motion to Dismiss or Bionpharma's First MTD	D.I. 8, Defendant Bionpharma's Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6)
Bionpharma's Notice Letter	Bionpharma's October 30, 2018 Paragraph IV Certification Notice Letter, attached hereto as Exhibit A
CCLS	Counterclaims
CoreRx	Non-party CoreRx, Inc., the supplier of Bionpharma's ANDA product and Azurity's corporate sister
CoreRx Suits	The Delaware and Florida CoreRx suits
Delaware CoreRx suit	*Azurity Pharm., Inc. v. CoreRx, Inc.*, C.A. No. 21-1522-LPS
DOE	Doctrine of equivalents
First Amended Complaint	D.I. 89, First Amended and Supplemental Complaint
First Wave Patents	'008, '442, '745, and '987 patents
First Wave Suits	*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962 and 19-1067 (D. Del.)
Florida CoreRx suit	*Azurity Pharm., Inc. v. CoreRx, Inc.*, No. 8:21-cv-2515 (M.D. Fla.)
JSD	Joint Stipulation of Dismissal entered in the Second Wave Suits (20-1256 D.I. 106)
NL	Notice Letter

Abbreviation	Meaning
Noerr-Pennington	The *Noerr-Pennington* doctrine, based on *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965).
NovaQuest	Non-party NovaQuest Capital Management, the private equity firm that owns Azurity and CoreRx
Paragraph IV certification	Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)
PI	Preliminary injunction
POSA	Person of ordinary skill in the art
Prior Kit Litigation	*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, No. 16-cv-876-MSG (D. Del.)
PTO or Patent Office	United States Patent and Trademark Office
Second Wave Patents	’868, ’482, and ’621 patents
Second Wave Suit	*Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. No. 20-1256 (D. Del.)
7/13/21 Shrestha Declaration	D.I. 9, July 13, 2021 Declaration of Roshan P. Shrestha, Ph.D.
TA	Tentative approval, *see* 21 C.F.R. § 314.107(b)(4)
Third Wave Patents	The ’023 and ’405 patents
Third Wave Suits	*Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.*, C.A. Nos. 21-1286-LPS, 21-1455-LPS (D. Del.)

Defendant Bionpharma respectfully submits this Opposition to Plaintiff Azurity's Motion to dismiss or bifurcate and stay Bionpharma's antitrust counterclaims. D.I. 148; 21-1455 D.I. 60.

INTRODUCTION AND SUMMARY OF ARGUMENT

The instant Third Wave Suits represent the latest in the continuing anticompetitive scheme Azurity has engaged in over the last 3+ years to improperly exclude Bionpharma's 1 mg/ml enalapril maleate oral solution—recently approved by the FDA under ANDA No. 212408 as generic to Azurity's Epaned® antihypertensive prescription drug product—from the market. Shortly after Bionpharma filed its ANDA with the FDA, Azurity instituted the First Wave Suits to trigger the 30-month stay of FDA approval of Bionpharma's ANDA (21 U.S.C. § 355(j)(5)(B)(iii)). At that time, Azurity only held the First Wave Patents, which were directed to a very narrow group of enalapril liquids. Bionpharma notified Azurity in its Paragraph IV Certification Notice Letters that it had designed around the First Wave Patents completely, and that Azurity had no possible claim for infringement. Bionpharma offered Azurity a pre-suit copy of its ANDA for review with reasonable confidentiality restrictions (as permitted by law), but—without any rational justification—Azurity refused to receive and review the ANDA and went ahead and instituted the First Wave Suits anyway. This Court held a 5-day bench trial in the First Wave Suits on February 1-5, 2021, and, on April 29, 2021, entered judgment of non-infringement for Bionpharma based on multiple legal and factual grounds. The Federal Circuit summarily affirmed on March 9, 2022.

Shortly after Bionpharma filed its ANDA, Azurity began filing patent applications seeking claim coverage well beyond what it actually invented (the narrow group of enalapril liquids claimed in the First Wave Patents) in a blatant attempt to cover Bionpharma's ANDA product, and eventually secured issuance of the Second Wave Patents. The Second Wave Patents claimed

enalapril liquids that Azurity simply never invented (and, therefore, never described and enabled in its patents) and were thus invalid upon issuance, something Azurity knew or clearly should have known. Despite this, Azurity instituted the Second Wave Suit and sought to preliminarily enjoin Bionpharma from launching its ANDA product. However, this Court's decision in the First Wave Suits doomed the Second Wave Suit, and the parties stipulated to dismissal.

As part of its overall anticompetitive scheme, Azurity implemented a strategy of serially filing patent applications claiming essentially the same, but slightly broader, subject matter, and securing patents with patentably indistinct claims at different times, in order to sue competitors like Bionpharma continually and at different times, in a purposeful effort to drive up litigation costs for competitors, forestall generic competition, and maintain monopoly power. This strategy has allowed Azurity to stagger its suits against Bionpharma in a way that has mired Bionpharma for over three years in continuous litigation involving the same accused product and patents claiming essentially the same subject matter, in a deliberate attempt to drive Bionpharma from the market—not by the merits of Azurity's patents, but with overwhelming litigation costs. The Third Wave Patents asserted in the instant suits—which, as with the Second Wave Patents, claim subject matter Azurity never invented, as it knows or should know—are just the latest example.

Finally, as part of its overall anticompetitive scheme, and in an attempt to regain its monopoly following Bionpharma's launch, Azurity went so far as to tortiously interfere in the supply of Bionpharma's ANDA product by filing sham suits against Azurity's own corporate sister, CoreRx, which, prior to being acquired by Azurity's private equity owner, had contracted with Bionpharma to manufacture and supply Bionpharma's ANDA product.

In order to redress this egregious course of anticompetitive conduct that has harmed, and continues to harm, Bionpharma and consumers, Bionpharma has filed counterclaims for

monopolization and attempted monopolization. D.I. 135, CCLS at Count III-IV; 21-1455 D.I. 46, CCLS Counts III-IV.[2] Azurity argues Counts III and IV fail to state a claim because: (1) Bionpharma's monopolization claims are allegedly barred because they were compulsory and should have been asserted in the First Wave Suits (D.I. 149, Azurity's Br. 7-8); (2) the *Noerr-Pennington* doctrine allegedly bars them (*id*. at 8-17); and (3) Bionpharma has allegedly failed to sufficiently plead the substantive elements of an antitrust claim (*id*. at 17-19). Alternatively, Azurity requests that the antitrust claims be severed and stayed. *Id*. at 19-20. As explained below, Azurity's Motion is meritless. ***First***, when Bionpharma answered in the First Wave Suits, its monopolization claims had not yet accrued, and were thus not compulsory. ***Second***, Azurity's *Noerr-Pennington* arguments simply dispute Bionpharma's factual allegations, and are thus improper grounds for dismissal. ***Third***, contrary to Azurity's assertion, Bionpharma has adequately pleaded all required elements of its antitrust claims. ***Finally***, Azurity's bifurcation request fails as Azurity admits that discovery for the antitrust and patent claims in these cases will overlap, Azurity's attempt to re-litigate the case schedule violates the "law of the case" doctrine, and there is little risk of jury confusion. Azurity's Motion should be denied.

NATURE AND STAGE OF THE PROCEEDINGS

Bionpharma and Azurity have been litigating Bionpharma's ANDA product and Azurity's enalapril liquid patents for over three years in this Court, starting with the First Wave Suits, which ended in a final judgment in Bionpharma's favor that was summarily affirmed on appeal; continuing with the Second Wave Suit, which was dismissed with prejudice (as Azurity conceded it could not prevail in the suit); and now continuing with the instant Third Wave Suits.

After the First and Second Wave Suits failed in this Court, Azurity instituted the 21-1286

[2] Bionpharma's antitrust counterclaims in the 21-1286 and 21-1455 suits are, for purposes of Azurity's Motion, essentially identical. All citations herein will be to the 21-1286 counterclaims.

action in the District of New Jersey on June 22, 2021 (as No. 3:21-cv-12870), asserting that Bionpharma's ANDA and ANDA product infringe the '023 patent (D.I. 1, Compl.). On September 10, 2021, however, that court blocked Azurity's attempt to avoid this forum, granting Bionpharma's § 1404(a) motion to transfer the suit here. D.I. 57. On July 14, 2021 (prior to transfer), Bionpharma filed its First Motion to Dismiss the original complaint on claim preclusion grounds based on the final judgment entered in the First Wave Suits and the JSD entered in the Second Wave Suits. D.I. 8. On October 15, 2021, Azurity instituted the 21-1455 suit alleging infringement of the '405 patent. 21-1455 D.I. 1. On November 10, 2021, this Court denied Bionpharma's First Motion to Dismiss without prejudice to re-file the motion later, and granted Azurity leave to file an amended complaint, but also denied Azurity's TRO/PI motion, citing "substantial questions" about the '023 patent's validity. D.I. 87, Oral Order; D.I. 96, 11/10/21 Hr'g Tr. 103:19-22, 115:11-17. On December 6, 2021, Bionpharma filed a second, successive motion to dismiss the First Amended Complaint in the 21-1286 action and a motion to dismiss the Complaint in the 21-1455 action on claim preclusion grounds based on Fed. R. Civ. P. 41(a)(1)(B). D.I. 97; 21-1455 D.I. 12. This Court denied Bionpharma's Second Motion to Dismiss on January 27, 2022. D.I. 124. On February 17, 2022, Bionpharma answered the operative complaints in the instant Third Wave Suits and filed antitrust counterclaims. The instant Motion followed.

FACTUAL BACKGROUND

I. STATUTORY FRAMEWORK

Bionpharma respectfully directs the Court's attention to paragraphs 28-33 of Bionpharma's Counterclaims (D.I. 135) for an explanation of the Hatch-Waxman framework.

II. BIONPHARMA'S ANDA AND ANDA PRODUCT

Bionpharma filed its ANDA in August 2018, seeking FDA approval to market its ANDA product as generic to Azurity's Epaned®. D.I. 135, CCLS ¶ 63. Bionpharma had designed its

ANDA product completely around Azurity's First Wave Patents, including by entirely omitting a buffer from its formulation, and by utilizing a preservative (methylparaben and propylparaben) that was disclosed in the specification[3] as an alternative to the claimed sodium benzoate but never claimed. *Id.* ¶¶ 61-62. Bionpharma's ANDA contained Paragraph IV certifications for the First Wave Patents that had issued by that time ('008, '442, '745 patents)[4] certifying, *inter alia*, that Bionpharma's ANDA product would not infringe them. *Id.* ¶ 63. Bionpharma provided Azurity with notice of its Paragraph IV certifications, which included a detailed statement of the factual and legal bases for Bionpharma's certifications. *Id.* ¶¶ 64-71; Ex. A, Bionpharma's October 30, 2018 Paragraph IV Certification Notice Letter ("Bionpharma's Notice Letter")[5]; 21 U.S.C. 355(j)(2)(B)(iv)(II). Bionpharma's Notice Letter explained in detail that Azurity had no claim for infringement because Bionpharma had omitted entirely from its formulation the claimed buffer and preservative, and because prosecution history estoppel and claim vitiation foreclosed any reliance by Azurity on the DOE. D.I. 135, CCLS ¶¶ 63-64; Ex. A, Bionpharma's NL at 8-42.

Bionpharma's Notice Letter included an offer of confidential access ("OCA") to Bionpharma's ANDA, with reasonable restrictions on the use of the information contained therein, as permitted by law. D.I. 135, CCLS ¶ 65; 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc); *id.* at § 355(j)(5)(C)(i)(I). Specifically, because Azurity's outside litigation counsel (Wilson Sonsini) was also Azurity's patent prosecution counsel, and because Azurity still had prosecution for its enalapril liquid patent family open at the PTO, Bionpharma's OCA included a provision restricting

[3] All of the patents in Azurity's enalapril liquid family contain essentially the same specification.
[4] Bionpharma's ANDA was later amended to include a Paragraph IV certification for the later issued '987 patent, which was the subject of the second of the First Wave Suits (19-1067).
[5] In analyzing Azurity's Motion, this Court "may consider documents 'integral to or explicitly relied upon in the complaint…without converting the motion…into one for summary judgment.'" D.I. 149, Azurity's Br. at 4 n.3 (quoting *Doe v. Univ. of the Scis.*, 961 F.3d 203, 208 (3d Cir. 2020)). Bionpharma's counterclaims explicitly rely upon Bionpharma's Notice Letter. *See, e.g.*, D.I. 135, CCLS ¶¶ 64-71.

access to Bionpharma's ANDA to only Azurity's outside counsel who did not engage in patent prosecution related to enalapril. D.I. 135, CCLS ¶¶ 65-69. Bionpharma believed its restrictions would be non-controversial given that in prior litigation between the same parties and involving the predecessor product to Epaned®, the Epaned® Kit (*Silvergate Pharm., Inc. v. Bionpharma Inc.*, No. 16-cv-876-MSG (D. Del.)), Azurity had agreed to the same restrictions. With no rational justification, Azurity refused to accept the OCA, thereby willfully blinding its counsel to Bionpharma's ANDA and the conclusive evidence of non-infringement. *Id.* ¶ 68-70.

III. THE FIRST WAVE SUITS

Thus, without even reviewing Bionpharma's ANDA, Azurity instituted the First Wave Suits alleging that Bionpharma's ANDA and ANDA product infringe the First Wave Patents. *Id.* ¶ 72. The First Wave Patents' claims are directed to: (1) a group of enalapril liquids that contain citric acid and sodium citrate as a buffer system at specific concentrations, sodium benzoate as a preservative at specific concentrations, and that are stable for 12 months at refrigerated conditions (5±3 °C); and (2) methods of treatment using those liquids. *Id.* ¶¶ 57-58. As explained above, Bionpharma had designed its ANDA product completely around the First Wave Patents, relying on narrowing claim amendments and express disclaimers Azurity made during prosecution to avoid infringement. *Id.* ¶¶ 61-62. Thus, Azurity had no objective basis to bring the First Wave Suits. *Id.* ¶¶ 160-64. The Court held trial on February 1-5, 2021 and, on April 27, 2021, issued its Opinion finding the asserted claims of the First Wave Patents not infringed, including because Azurity failed to prove the existence of a buffer in Bionpharma's ANDA product. *Id.* ¶¶ 93-97. The Court entered final judgment for Bionpharma shortly thereafter. *Id.* ¶ 98. On March 9, 2022, the Federal Circuit summarily affirmed. *Azurity Pharm., Inc. v. Bionpharma Inc.*, Nos. 2021-1926, -1927, 2022 WL 703903 (Fed. Cir. Mar. 9, 2022). Azurity could not have reasonably expected any different result from the courts, but it got what it obviously wanted: the 30-month

stay, which excluded Bionpharma's ANDA product from competing against Epaned® until its expiration on April 30, 2021, four months after the FDA granted TA to Bionpharma's ANDA. D.I. 135, CCLS ¶¶ 189, 194.

IV. THE SECOND WAVE SUIT

Shortly after Bionpharma filed its ANDA, Azurity began filing continuation patent applications seeking broader claim coverage, and eventually secured issuance of the Second Wave Patents in late 2020, which were the subject of the Second Wave Suit (filed September 18, 2020). *Id.* ¶¶ 99, 107; 20-1256 D.I. 1. As was made clear during prosecution of the First Wave Patents, because enalapril was an old drug and because enalapril liquids were well known in the prior art, the PTO would grant Azurity patents only on enalapril liquids that it had described in the specification as being stable at refrigerated conditions for at least 12 months—the Example E liquids, which all contained specific concentrations of citric acid, sodium citrate, and sodium benzoate—as the PTO felt that the 12-month stability demonstrated for those liquids was unexpected and warranted patent protection. *Id.* ¶¶ 45-56; *Silvergate Pharm., Inc. v. Bionpharma Inc.*, C.A. Nos. 18-1962, 19-1067, 2021 WL 1751148, *9-14 (D. Del. Apr. 29, 2021). Nevertheless, during prosecution of the applications that issued into the Second Wave Patents, Azurity was able to leverage the PTO examiner's mistaken belief that Azurity could supplement its deficient written description through inventor declarations submitted after the applications were filed to secure issuance of claims covering stable enalapril liquids that use buffers beyond citric acid/sodium citrate, and preservatives beyond sodium benzoate—claims that go well beyond Example E and that were nowhere described in the specification. D.I. 135, CCLS ¶¶ 99-105.

In March of 2021, fearing the impending expiration of the 30-month stay and a loss in the First Wave Suits, Azurity moved for a PI based on the Second Wave Patents. *Id.* ¶ 108. But because all of the Second Wave Patents' claims require a buffer, this Court's finding in the First

Wave Suits that Azurity failed to prove the existence of a buffer doomed the Second Wave Suit, and the parties stipulated to dismissal with prejudice, which was so ordered on May 21, 2021. *Id.* ¶ 111. Azurity also knew or should have known that the Second Wave Suit was objectively baseless before it filed the suit because it knew or should have known that the Second Wave Patents' claims were invalid for lack of written description and enablement. *Id.* ¶¶ 165-69.

V. THE THIRD WAVE SUITS

In early 2021, Azurity continued with its strategy of serially filing applications claiming slightly broader versions of essentially the same subject matter in an attempt to cover Bionpharma's ANDA product, which was beyond the reach of Azurity's First and Second Wave Patents. *Id.* ¶¶ 112-31. Azurity eventually secured the Third Wave Patents, which essentially cover enalapril liquids that may or may not contain a buffer, and that are stable for at least 12 months at refrigerated conditions—well beyond the Example E liquids. *Id.* ¶¶ 131-43. Azurity knew, or should have known, before filing the Third Wave Suits that the Third Wave Patents were invalid for lack of written description and enablement. *Id.* ¶¶ 135, 144. On November 10, 2021, this Court denied a TRO/PI motion Azurity filed to remove Bionpharma's ANDA product (launched on August 17, 2021) from the market, finding "substantial questions" regarding the validity of the '023 patent. *Id.* ¶¶ 140, 145.

VI. THE CORERX SUITS

In late 2020, Bionpharma contracted with CoreRx—the company that, in collaboration with Bionpharma, developed Bionpharma's ANDA product—to commercially manufacture and supply Bionpharma's ANDA product after Bionpharma secured final FDA approval. *Id.* ¶¶ 13, 15, 60-61. In early 2021, NovaQuest, the private equity firm that owns Azurity, acquired CoreRx. *Id.* ¶¶ 16-17. Since then, Azurity and CoreRx have been corporate sisters controlled and dominated by NovaQuest, and, at any given time, four or five of Azurity's board members have sat on

CoreRx's seven-member board. *Id.* ¶¶ 18-24. In late October 2021—sensing it was going to lose its TRO/PI motion in the 21-1286 case, and in an attempt to cut off Bionpharma's supply—Azurity sued CoreRx in this Court and in the Middle District of Florida, asserting that CoreRx's manufacture and supply of Bionpharma's ANDA product infringed the Third Wave Patents. *Id.* ¶¶ 146-47, 179. The CoreRx Suits were sham suits because Azurity and CoreRx never had any adverse interests as they are sister companies, and there was therefore never any case or controversy between the two. *Id.* ¶¶ 148-51. Azurity subsequently entered into a sham "settlement" with CoreRx whereby CoreRx agreed to stop supplying Bionpharma, and dismissed the CoreRx Suits. *Id.* ¶¶ 156-58.

ARGUMENT

I. LEGAL STANDARD

In reviewing Azurity's Motion, this Court is to "accept all factual allegations in the complaint as true and view them in the light most favorable to [Bionpharma]." *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006). Bionpharma's counterclaims should not be dismissed "unless [this Court] find[s] that [Bionpharma] can prove no set of facts that would entitle [it] to relief." *Id.*

II. AZURITY'S MOTION TO DISMISS SHOULD BE DENIED

A. Bionpharma's Monopolization Claims Are Not Barred

"Rule 13(a) does not require a defendant to file as a compulsory counterclaim a claim that has not yet accrued." *Med. Mut. of Ohio, Inc. v. Braintree Labs.*, Civ. No. 10-604-SLR, 2011 WL 2708818, at *4 (D. Del. July 12, 2011). While some courts have held that sham litigation claims accrue when the sham case is filed, courts have also recognized that the accrual date is tolled if either: (1) the defendant committed continuing violations of the Sherman Act "inflicting continuing and accumulating harm"; or (2) "damages flowing from [the] alleged anticompetitive

conduct were unascertainable at the time [the defendant] engaged in such conduct." *Id*. at *5 (citing *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 401 U.S. 321, 338-39 (1971) ("*Zenith II*"); *West Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 106 (3d Cir. 2010); *see also* Ex. B, 3 P. Areeda & H. Hovenkamp, *Antitrust Law* ¶ 706e (4th ed. 2015) (criticizing strict treatment of sham litigation counterclaims as compulsory "when the facts needed to support the counterclaim are not sufficiently known at the time the infringement action is brought"); Ex. C, H. Hovenkamp, et al., *IP and Antitrust* § 5.05[B][6] (3d ed. 2016, Supp. 2021) ("*IP and Antitrust*") (similarly). Azurity's assertion that Bionpharma's monopolization claims (Count III) were compulsory and should have been raised in the First Wave Suits is incorrect for two reasons.

First, as Azurity recognizes, one theory Bionpharma has pleaded in support of its monopolization claims is based solely on the sham First Wave Suits. However, Bionpharma's monopolization claims based on that theory had not yet accrued when Bionpharma answered the complaints in those suits (December 17, 2019; *see* 18-1962 D.I. 37, 19-1067 D.I. 24) because Bionpharma did not have TA for its ANDA product then. *Med. Mut.*, 2011 WL 2708818, at *5. Bionpharma did not receive TA until December 28, 2020 (D.I. 135, CCLS ¶ 218); "prior to this point, damages [we]re 'entirely speculative' since it [was] unclear 'whether FDA itself would even approve [Bionpharma's ANDA]' in the first instance." *Id*. (quoting *In re Relafen Antitrust Litig.*, 286 F. Supp. 2d 56, 63 (D. Mass. 2003)).

Second, while the sham First Wave Suits are one theory Bionpharma has pleaded in support of its monopolization claims, Bionpharma has also ***separately and independently*** pleaded an overall anticompetitive scheme perpetrated by Azurity in support of its monopolization claims[6]

[6] In Count III, Bionpharma expressly pleaded that "Azurity has engaged in exclusionary and predatory conduct, ***including, without limitation***, the filing and prosecution of the sham First Wave Suits." D.I. 135, CCLS ¶ 239 (emphasis added). The first paragraph of Count III "repeats and incorporates herein by reference [the] counterclaim paragraphs above," which include facts

based on at least the following conduct: (1) the filing of the sham First Wave Suits (D.I. 135, CCLS ¶¶ 45-98); (2) the filing of the sham Second Wave Suit (*id*. ¶¶ 99-111); (3) Azurity's misuse of the PTO process (*id*. ¶¶ 112-130); and (4) the filing of the sham Third Wave Suits (*id*. ¶¶ 131-145). *See also id*. ¶¶159-183; *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 428 (D. Del. 2006) ("Plaintiffs are entitled to claim that individual acts are antitrust violations, as well as claiming that those acts as a group have an anticompetitive effect even if the acts taken separately do not."); *Rochester Drug Co-Op v. Braintree Labs.*, 712 F. Supp. 2d 308, 318-19 (D. Del. 2010) (recognizing an overall anticompetitive scheme pleaded and that the "court need not…analyze whether each facet of this scheme constitutes a separate antitrust violation."); *In re Gabapentin Patent Litig.*, 649 F. Supp. 340, 359 (D.N.J. 2009) (recognizing that "courts have routinely upheld the validity of 'overall monopolization scheme' claims in the patent context."); *id*. at 366 (recognizing that manipulation of PTO process to delay patent issuance and serially institute sham litigation may support "viable antitrust claim[s]"). The accrual date for Bionpharma's monopolization claims based on this overall scheme is the date of the last overt act—the June 22, 2021 filing date of the 21-1286 suit (the first of the Third Wave Suits), which occurred well after Bionpharma answered in the First Wave Suits (December 17, 2019 (18-1962 D.I. 37)). *West Penn*, 627 F.3d at 105-07; *Med. Mut.*, 2011 WL 2708818, at *5. Bionpharma's monopolization claims are not barred.

B. *Noerr-Pennington* Does Not Bar Bionpharma's Claims

The *Noerr-Pennington* doctrine immunizes from antitrust liability "those who petition the government for redress," and "includes the right to sue in federal court." *AbbVie*, 976 F.3d at 359-

Bionpharma has pleaded in support of its anticompetitive scheme theory. *Id*. ¶¶ 45-183; *FTC v. AbbVie Inc.*, 976 F.3d 327, 348 (3d Cir. 2020) (monopolization count that "realleges and incorporates by reference" preceding complaint allegations was not based solely on sham litigation theory expressly recited in the count, but also on reverse-payment theory pleaded earlier).

60 (internal quotations and brackets omitted). One exception is "if a lawsuit is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." *Id.* at 360 (internal quotations omitted). For the sham litigation exception to apply, the lawsuit must be objectively baseless and subjectively motivated to interfere directly with the competitor's business relationships. *Id.* (citing *Prof'l Real Estate Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60-61 (1993) ("*PRE*")). If the antitrust defendant had no probable cause to bring suit, the suit is objectively baseless. *Id.*

1. Count III (Monopolization)

Azurity focuses its *Noerr-Pennington* arguments on only one theory supporting Count III—the sham First Wave Suits—but it entirely ignores that Bionpharma has pleaded in support of Count III an anticompetitive scheme based on not only the filing of the sham First Wave Suits, but also based on the filing of the sham Second and Third Wave Suits, and Azurity's misuse of the PTO prosecution process. Under either theory, Bionpharma has pleaded facts that plausibly demonstrate that Azurity had no probable cause to sue Bionpharma in each wave.[7]

a. Monopolization based on the First Wave Suits

As shown above, Bionpharma has pleaded that it filed Paragraph IV certifications for the First Wave Patents asserting that, *inter alia*, Bionpharma's ANDA product did not infringe those patents, and that Bionpharma provided Azurity with its Notice Letter explaining in detail why there could be no infringement: Bionpharma had omitted entirely from its ANDA product the

[7] Azurity's assertion that the objectively-baseless inquiry is frozen at the time the alleged sham suit is filed, and that post-filing activity is irrelevant (D.I. 149, Azurity's Br. 10-11), is based on an overly narrow reading of *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3d Cir. 2017). *See* Ex. C, *IP and Antitrust* §§ 11.03[A] n.114, 11.03[B][2] ("[I]f the IP owner becomes aware during the course of the infringement litigation that the lawsuit is objectively baseless and continues to pursue the lawsuit in order to harm its competitor through the litigation process, the litigation could be considered a sham for antitrust purposes." (citation omitted)). For brevity, Bionpharma focuses on its allegations that Azurity's suits were objectively baseless when filed.

claimed buffer and sodium benzoate preservative. D.I. 135, CCLS ¶¶ 61-64; Ex. A, Bionpharma's NL at 8-19. Bionpharma's Notice Letter also explained in painstaking detail why DOE infringement was foreclosed based on amendment- and argument-based estoppel, and based on claim vitiation. *Id*. Bionpharma thus has expressly pleaded facts plausibly showing that the First Wave Suits were objectively baseless. D.I. 135, CCLS ¶¶ 160-64. These facts must be assumed true. In asserting that "Bion's bare non-infringement positions in its Paragraph IV Certification were unsupported and unsubstantiated" (D.I. 149, Azurity's Br. at 11), Azurity is simply disputing the predicate facts alleged, which is insufficient grounds for dismissal.[8] *Buck*, 452 F.3d at 260; *Gabapentin*, 649 F. Supp. 2d at 363 ("[W]hen predicate facts of an allegedly sham lawsuit are disputed, sham litigation claims should not be decided by the court as a matter of law."); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 210 (E.D. Pa. 2011) (whether litigation is a sham is "generally a question of fact for the jury" (internal quotations omitted)); *id*. ("A court should only rule on the objective baselessness prong as a matter of law '[w]here there is no dispute over the predicate facts of the underlying [litigation].'" (quoting *PRE*, 508 U.S. at 60-61)).

Next, Bionpharma has pleaded that Azurity failed in its duty (under, *e.g.*, Rule 11) to carry out a reasonable investigation of its infringement claims before filing the First Wave Suits by refusing to accept Bionpharma's OCA—whose reasonable confidentiality restrictions Azurity

[8] That Bionpharma was denied leave to file a Rule 12(c) motion, and that Bionpharma did not move for summary judgment (D.I. 149, Azurity's Br. 11-12), are irrelevant, as the Court's decision denying Bionpharma leave was a discretionary one made based primarily on Azurity's argument that the parties were too close to trial. 18-1962 D.I. 135, 5/5/20 Hr'g Tr. 55:19-58:6, 72:6-20; 18-1962 D.I. 168, 12/1/20 Hr'g Tr. 48:7-9; *Almirall, LLC v. Torrent Pharm., Ltd.*, 548 F. Supp. 3d 443, 451 (D. Del. 2021) (12(c) motion is discretionary and because Hatch-Waxman cases are often bench trials, estoppel will almost always be decided after trial). Further, the 12(c) motion Bionpharma sought leave to file did not involve its factual defenses underlying Counts III-IV. *Compare* 18-1962 D.I. 58 at 4-9, *with* D.I. 135, CCLS ¶¶ 160-83; *Abbott*, 432 F. Supp. 2d at 426 (summary judgment opinion that did not address certain antitrust allegations pleaded was irrelevant to the probable cause determination).

previously had agreed to during the Prior Kit Litigation and ultimately agreed to in the First Wave Suits—and to receive and review Bionpharma's ANDA, which contained irrefutable evidence that Azurity had no probable cause to sue. D.I. 135, CCLS ¶¶ 62-71, 162. Azurity's assertion that Bionpharma fails to "detail[] what those so-called 'reasonable' restrictions were" (D.I. 149, Azurity's Br. 14) simply ignores paragraphs 62-71 and 162 of Bionpharma's counterclaims. At best, Azurity is simply disputing the facts alleged in those paragraphs, which is insufficient for dismissal. *Abbott*, 432 F. Supp. 2d at 426 (Defendant's contention that it was not required to carry out pre-suit testing of the ANDA product "was contrary to the allegations, viewed in the light most favorable to Plaintiffs, and cannot support the Motion to Dismiss."). Bionpharma has adequately pleaded facts that plausibly demonstrate that Azurity had no objective basis to file suit.[9]

With respect to the subjective prong, Bionpharma has also alleged that Azurity refused to investigate its claims before instituting suit, showing its indifference to its chances of judicial relief, and brought suit simply to trigger the 30-month stay to forestall generic competition and buy more time to serially file additional patent applications regardless of their inherent and obvious invalidity. D.I. 135, CCLS ¶¶ 62-71, 162-63; Ex. A, Bionpharma's NL at 8-19. In asserting that it was simply trying to "[d]efend [i]ts [r]ights and [c]omply with the Hatch-Waxman Act" (D.I. 149 Azurity's Br. 13), Azurity is doing nothing more than disputing the predicate facts that Bionpharma has pleaded, which is insufficient for dismissal. Azurity's argument ignores *AbbVie*'s holding that the subjective prong is satisfied by a showing that "a defendant was indifferent to the outcome of its infringement suit, and the automatic, 30-month stay was an anticompetitive weapon

[9] Azurity's suggestion that a Paragraph IV certification gives a brand probable cause to sue because of the Hatch-Waxman framework (D.I. 149, Azurity's Br. 9, 14) ignores *AbbVie*'s rejection of *Noerr-Pennington* immunity for sham ANDA litigation: courts "must not immunize a brand-name manufacturer who use [Hatch-Waxman's] automatic, 30-month stay to thwart competition." *AbbVie*, 976 F.3d at 361, 366-71.

the defendant tried to wield." *AbbVie*, 976 F.3d at 361, 368-71.

b. Monopolization Based on Azurity's Overall Anticompetitive Scheme

Azurity did not even address the separate, independent theory supporting Bionpharma's monopolization claim—that Azurity engaged in a course of anticompetitive conduct, including by filing the sham First, Second, and Third Wave Suits, and by misusing the PTO prosecution process. Under the facts Bionpharma has pleaded, none of the sham suits in this scheme is entitled to *Noerr-Pennington* immunity. As explained above, Azurity had no probable cause to institute the First Wave Suits. Nor did Azurity have probable cause to institute the Second and Third Wave Suits; the Second and Third Wave Patents were invalid the moment they were issued. D.I. 135, CCLS ¶¶ 165-74. Bionpharma has alleged in detail why the Second and Third Wave Patents are invalid and why Azurity knew or should have known this before instituting suit (*id.* at ¶¶ 45-59, 99-111, 131-45). With respect to Azurity's' subjective motivation, Bionpharma has pleaded facts plausibly showing that Azurity filed the First Wave Suits to improperly secure the 30-month stay solely to delay final approval of Bionpharma's ANDA, and filed the Second and Third Wave Suits not to win those suits, but to mire Bionpharma in never-ending litigation to drive up costs for Bionpharma and coerce it into exiting the market. *Id.* at 184-88. These detailed facts must be assumed true; merely contesting them does not sustain Azurity's burden. *Buck*, 452 F.3d at 260.

2. Count IV (Attempted Monopolization)

Azurity's *Noerr-Pennington* arguments with respect to Bionpharma's attempted monopolization claim (Count IV) once again dispute the predicate facts that Bionpharma has pleaded, and are therefore insufficient grounds for dismissal. *Flora v. Cnty. of Luzerne*, 776 F.3d 169, 175 (3d Cir. 2015) (In deciding a motion to dismiss, "[t]he district court may not make findings of fact and, insofar as there is a factual dispute, the court may not resolve it."). In Count

IV, Bionpharma has alleged Azurity's anticompetitive scheme consisting of (at least) Azurity's filing of the sham Third Wave and CoreRx Suits. D.I. 135, CCLS ¶¶ 245-52. Specifically, Bionpharma has alleged that Azurity had no probable cause to institute: (1) the Third Wave Suits because the Third Wave Patents were invalid the moment they issued (something Azurity knew or should have known); and (2) the CoreRx Suits because Azurity and CoreRx are sister companies owned and controlled by NovaQuest, with essentially the same board members, and, thus, there was never any justiciable controversy between adverse litigants sufficient to support subject matter jurisdiction over Azurity's claims against CoreRx. *Id.* ¶¶ 16-25, 45-59, 131-35, 138, 142-51. The statutory presumption of validity for patents Azurity relies on (D.I. 149, Azurity's Br. 14-15) is overcome by Bionpharma's express allegations plausibly showing that the Third Wave Patents are indisputably invalid. For the CoreRx Suits, Azurity disputes the predicate facts Bionpharma has pleaded regarding Azurity's relationship with CoreRx (*id.* at 15-16 (arguing that Bionpharma "improperly conflates parent-subsidiary corporate relationships…with portfolio company relationships" and relying on the "presumption of corporate separateness")—again, these fact disputes are insufficient for dismissal.

With respect to the subjective prong, Azurity again disputes the predicate facts that Bionpharma has alleged, including that Azurity filed the Third Wave and CoreRx Suits not to prevail on the merits, but to increase litigation costs for Bionpharma, wear it down, and coerce it into abandoning its ANDA product, and to create a legal "justification" through a sham settlement for CoreRx to breach its supply agreement with Bionpharma. D.I. 135, CCLS ¶¶ 187-88. Azurity's assertion that Bionpharma was required to allege that the "Third [Wave] Patents have been declared invalid or unenforceable," that "CoreRx could plausibly argue non-infringement," and that Azurity's "enforcement of its patent rights [is] somehow atypical" (D.I. 149, Azurity's

Br. 16-17) is meritless—Bionpharma has alleged that those patents are invalid (and that Azurity knew or should have known this), and that must be assumed true; whether Azurity's conduct in asserting invalid patents, even against its commonly-owned affiliate, is "atypical" is irrelevant.

C. Bionpharma Has Properly Pleaded Its Antitrust Claims

Although Azurity uses the label "antitrust injury" when asserting that Bionpharma has not pleaded all required elements of its antitrust claims, Azurity is really arguing only that Bionpharma failed to allege causal injury-in-fact—that Azurity proximately caused Bionpharma's injury. D.I. 149, Azurity's Br. 17-19. Bionpharma has pleaded facts plausibly demonstrating a direct link between Azurity's scheme and Bionpharma's injury, and Bionpharma has pleaded facts plausibly showing Azurity's specific intent to monopolize the relevant market.

Count III (monopolization): Once again ignoring the overall scheme Bionpharma has pleaded, Azurity focuses on the First Wave Suits, arguing that Bionpharma has not pleaded facts to explain why it "waited over three and a half months [after conclusion of the First Wave Suits] to launch its product on August 17, 2021," or facts showing that Azurity, not FDA, caused any delay of Bionpharma's launch after the First Wave Suits ended. D.I. 149, Azurity's Br. 17. But these arguments go to the amount of harm Azurity caused Bionpharma—exclusion from December 2020 to either (1) April 29, 2021 (resolution of the First Wave Suits), or (2) August 17, 2021 (the date Bionpharma launched)—not whether Bionpharma actually sustained injury proximately caused by Azurity's baseless pursuit of the 30-month stay. *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 395 U.S. 100, 114 n.9 (1969) ("*Zenith I*") (antitrust plaintiff may establish injury with "proof of some damage flowing from the unlawful [conduct]; inquiry beyond this minimum point goes only to the amount and not the fact of damage.").

Bionpharma ***did not*** need to plead facts "as to how [it] would have obtained final approval [on December 28, 2020] and whether and when it was commercially prepared to launch." D.I.

149, Azurity's Br. 17; *In re Niaspan Antitrust Litig.*, 42 F. Supp. 2d 735, 756 (E.D. Pa. 2014) ("Plaintiffs are not required to plead detailed evidentiary matter in order to survive a motion to dismiss." (internal quotations and ellipses omitted)). Bionpharma need not "completely discredit in its initial pleadings all possible intervening causes of its delayed launch," nor "allege that [Azurity's] anticompetitive actions were the sole cause of its injury." *Gabapentin*, 649 F. Supp. 2d at 356 (citing *Zenith I*, 395 U.S. at 114 n.9)). Most importantly**,** however, Azurity ignores that Bionpharma's monopolization claims are also based on an overall anticompetitive scheme that includes the filing of the sham First, Second, and Third Wave Suits, and misuse of the PTO prosecution process, which allowed Azurity to improperly secure a 30-month stay, ***and also*** to raise litigation costs and mire Bionpharma in never-ending sham litigation. This anticompetitive scheme proximately caused the delay of entry of Bionpharma's ANDA product from December 28, 2020 (date of TA) until August 17, 2021 (launch) (D.I. 135, CCLS ¶¶ 189-94, 220-23), and this delay in competition "constitutes the relevant anticompetitive harm." *FTC v. Actavis, Inc.*, 570 U.S. 136, 157 (2013); *TransWeb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1308-12 (Fed. Cir. 2016) (attorney fees resulting from sham litigation are relevant antitrust injury).

Count IV (attempted monopolization): Azurity's argument that Bionpharma cannot plausibly allege injury because Azurity may yet win the Third Wave Suits (D.I. 149, Azurity's Br. 7-8) is meritless—taken to its logical conclusion, a party could never assert attempted monopolization as a counterclaim in a sham suit, which is vexing given Azurity's contention that sham litigation claims must be asserted when the sham litigation is filed (*id*. at 7-8). That Bionpharma pleaded that Azurity "could simply have ordered CoreRx to stop supplying Bionpharma," does not mean that the CoreRx Suits did not proximately harm Bionpharma (*id*. at 18): that Azurity had two anticompetitive acts to choose from—filing the sham CoreRx Suits and

directly ordering CoreRx breach its supply agreement—could not mean that the act it chose did not cause injury. Moreover, Bionpharma "need not allege (or dispose of) all alternative theories of causation to survive a motion to dismiss." *Gabapentin*, 649 F. Supp. 2d at 357 (internal quotations omitted). Finally, Azurity ignores the facts Bionpharma has pleaded plausibly demonstrating Azurity's specific intent to monopolize. *See* D.I. 135, CCLS ¶¶ 187-88, 219, 249.

III. AZURITY'S ALTERNATIVE MOTION SHOULD BE DENIED

Azurity's request to bifurcate and stay the antitrust counterclaims fails for several reasons. First, Azurity argument that "resolution of the patent claims [in the instant Third Wave Suits] will moot Bion's antitrust claims" (D.I. 149, Azurity's Br. at 19) ignores that one theory supporting Bionpharma's monopolization claims (Count III) is based solely on the filing of the sham First Wave Suits, which Bionpharma has already prevailed on; thus, even if Azurity prevails in the instant Third Wave Suits, Bionpharma's monopolization claims still stand.[10]

Second, Azurity's argument that bifurcation is necessary to speed up the patent case (*id*. at 19-20) reargues the length of the schedule, which the parties have already fiercely litigated; Judge Stark sided with Bionpharma, finding that a two-year schedule was justified even without antitrust counterclaims. D.I. 125, Oral Order. Azurity's attempt to re-litigate the law of the case should be rejected. *In re Cont'l Airlines*, 279 F.3d 226, 232-33 (3d Cir. 2002); *Gabapentin*, 649 F. Supp. 2d at 356-57 (applying law of the case to different judge's prior ruling in the same case). Azurity's assertion that Bionpharma "is currently marketing an infringing product" ignores this Court's conclusion that Azurity is unlikely to succeed on the merits. D.I. 87, Oral Order; D.I. 96, 11/10/21 Hr'g Tr. 103:9-24. Moreover, as Azurity has admitted, discovery on the antitrust claims will

[10] *Eagle Pharmaceuticals, Inc. v. Eli Lilly & Co.*, No. 18-1121-MSG, 2018 WL 6201704 (D. Del. Nov. 27, 2018) is distinguishable for that reason alone, and also because the antitrust discovery in these cases overlaps with the patent discovery to be taken. *Id*. at *2-3.

greatly overlap with discovery on Azurity's patent claims, D.I. 118, 1/20/22 Azurity Ltr. at 1-2; efficiency thus counsels against bifurcation. *Netflix, Inc. v. Blockbuster, Inc.*, No. C 06-2361 WHA, 2006 WL 2458717, at *10 (N.D. Cal. Aug. 22, 2006); *see also In re Theodor Groz & Söhne*, Misc. No. 338, 1992 WL 188908, at *2 (Fed. Cir. May 18, 1992) (affirming denial of bifurcation and stay due to "commonality of the patent and antitrust issues"); *Synopsys, Inc. v. Magma Design Automation*, No. CIV A 05-701(GMS), 2006 WL 1452803, at *4 (D. Del. May 25, 2006) (holding that bifurcation without case-specific reasons is improper under Rule 42). Indeed, Bionpharma's sham litigation claims are based on its patent defenses, Bionpharma has raised an unclean hands defense, and each side seeks damages—discovery will thus greatly overlap.

Third, Bionpharma disputes that a single trial will risk jury confusion. Bionpharma's antitrust claims are based on the patent issues raised in Azurity's patent suits, which the jury will hear evidence on by virtue of Bionpharma's invalidity defenses and the prosecution history. With the assistance of counsel, the jury can handle these issues in one trial. *Synopsys*, 2006 WL 1452803, at *4 (denying bifurcation and rejecting "jury confusion" argument). Nevertheless, this determination is premature—there is no need for this Court to decide at this stage how this case should be tried. *Netflix*, 2006 WL 2458717, at *10 ("The immediate task is discovery. By allowing both sides to develop their cases we will be in a better position later to decide the extent to which both cases should be tried to a jury.").

Finally, even if bifurcation is granted, Bionpharma respectfully requests denial of a stay and continuation of discovery because there will be considerable overlap. *Ecrix Corp. v. Exabyte Corp.*, 191 F.R.D. 611, 614 (D. Colo. 2000) (bifurcating but denying stay).

CONCLUSION

Azurity's Motion should be denied. Alternatively, Bionpharma respectfully requests leave to amend its Counterclaims.

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